

REMARKS

The Office Action mailed June 14, 2004, set a three-month shortened statutory period for response expiring September 14, 2004. The period for response is extended three months to December 14, 2004, pursuant to the Petition for Extension of Time under 37 C.F.R. 1.136(a) submitted herewith. This response is therefore timely filed.

New formal drawings, Figures 1A, 1B, 1C, 1D, 2A, 2B, 2C, 2D, 3, 4A, 4B, 4C, 4D, 5, 6, 7A, 7B, 7C, 7D, 7E, 7F, 8A, 8B, and 9, are submitted herewith.

Previous Figure 7D has been cancelled as this figure was inadvertently included in the amendments to the figures filed on June 19, 2001. Previous Figure 7D is a copy of original Figure 7b, and is a duplicate of previous Figure 7C (now Figures 7E and 7F), prior to the amendment of October 21, 1999.

Because of a larger font size used in preparation of formal drawings for the instant application, Figures 2C, 7A, 7B, and 7C were extended from one page to two pages. The figures, therefore, have been relabeled to reflect these extra pages, and the "Brief Description of the Drawings" has been amended in view of this change.

The specification has also been amended at page 23, line 36, and page 24, line 19 to reflect the above-mentioned changes in the labeling of the figures.

Claims 1-43 were in the application as originally filed. Claims 1-4, 37, and 39-43 were cancelled and claims 44-59 were added by the amendment filed on June 19, 2001. Claims 60-114 were added by the amendment filed on April 10, 2002. Claims 48-51, 74, 85, and 88 were cancelled by the amendment filed on December 19, 2002.

Before this amendment, claims 5-36, 38, 44-47, 52-73, 75-84, 86, 87, and 89-114 were in the application.

Non-elected claims 5-36, 38, 52-71, and 89-110 are cancelled herein without prejudice to the prosecution thereof in a continuing application.

Claims 72, 83, and 87 are amended by deleting therefrom the references to “biologically active fragments,” thereby more particularly defining Applicants’ preferred proteins.

Claims 78 and 111 are amended to more clearly and particularly define Applicants’ preferred nucleotide sequences, and to include the limitations of dependent claims 81 and 114, respectively. Claims 81 and 114 have been amended to reflect the amendments to claims 78 and 111.

Claim 87 has been amended to replace the terms “mature sequence,” “extracellular domain,” and “intracytoplasmic domain” of IL-13R β with the SEQ ID NO’s and specific amino acid sequences. Support for these amendments can be found, for example, on page 7, lines 24 to 28; page 23, line 21 to page 24, line 5; Figure 2; and in the Brief Description of the Drawings for Figure 2.

Claims 44-47, 72-73, 75-84, 86-87, and 111-114 remain in the application, and all but claim 45 stand rejected under 35 U.S.C. § 112. Applicants note that the previous rejection under 35 U.S.C. § 102(b) has not been maintained.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 72, 83, and 87 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite on the grounds that it is not clear what specific regions of the protein comprise a “biologically active fragment,” and what activity is contained in said fragment.

This rejection is believed overcome and should be withdrawn in view of the amendments to claims 72, 83, and 87 in which the phrases referring to a “biologically active fragment” have been deleted.

Claims 78 and 111 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the stated reason the phrases “stringent conditions” and “allelic variant” are not clearly defined so as to allow the metes and bounds of the claim to be determined.

This rejection is believed overcome and should be withdrawn in view of the amendments to claims 78 and 111 wherein the phrases referencing allelic variants have been deleted and the stringent conditions of hybridization have been more clearly defined.

Claim 87 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite on the grounds that it is not clear what are the “mature sequence of IL-13 receptor chain protein, IL-13R β ,” the “extracellular domain of sequence (a)” or “intracytoplasmic domain of sequence (a).” The Examiner also indicated that it is not clear what sequence (a) is and to what fragments (a)-(c) are referring. The Examiner suggests that IL-13R β be referred to by SEQ ID NO, and the domains be identified by a specific amino acid sequence to overcome this rejection.

Initially, Applicants note that the sequences of claim 87 should be labeled as (a)-(c) as shown above, not as (e)-(g). The sequences of Claim 87 were correctly labeled in the actual amendment filed on December 19, 2002, but were inadvertently mislabeled in the “Version with Markings to Show Changes Made,” filed with the amendment.

This rejection is believed overcome and should be withdrawn in view of the correct labels of (a)-(c) and the above-described amendments to claim 87 replacing the terms “mature sequence,” “extracellular domain,” and “intracytoplasmic domain” of IL-13R β with the SEQ ID NO’s and specific amino acid sequences, as suggested by the Examiner.

Claims 73, 75-77, 79-82, 84, 86, and 112-114 are held indefinite because they depend upon an indefinite base claim.

In view of the foregoing arguments, Claims 72, 78, 83 and 111 are believed to be allowable, and, accordingly, claims 73, 75-77, 79-82, 84, 86, 112-114 should be allowable in dependent form.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 44, 46-47, 72-73, 75-78, 81, 83-84, 86-87, and 111-114 are rejected under 35 U.S.C. § 112, first paragraph, apparently on the grounds that the specification, while being enabling for (a) the protein comprising the amino acid of SEQ ID NO: 2; (b) specific fragments of the protein of SEQ ID NO:2 which can inhibit the binding of IL-13 to the protein of SEQ ID NO:2, such as the fragment consisting of residues 1 to 337 of SEQ ID NO:2; and (c) specific fragments of the protein of SEQ ID NO:2 which are of sufficient length to be used as epitopic portions of the polypeptide of SEQ ID NO:2; does not provide enablement for other compounds not disclosed in subsections (a)-(c), above.

This rejection is traversed and reconsideration and withdrawal thereof are respectfully requested for the reasons given hereinbelow.

Applicants respectfully point out that claims 44, 46, and 47 are directed to one or more of the proteins of SEQ ID NO: 2, SEQ ID NO: 2 in which the 8 c-terminal residues are substituted by the 6 residues of SEQ ID NO: 11, SEQ ID NO: 2 from residue 1-343 and SEQ ID NO: 2 from residue 1-337. These proteins and the use thereof are clearly described in the specification e.g., in SEQ ID NO: 2 and Fig. 2A and 2B, and in the specification at page 6, lines 14-21; at Example 6, which describes the preparation of the polypeptide of SEQ ID NO: 2 from residues 1-337; and in Figs. 5 and 6, which show the use thereof in the inhibition of IL-13 binding. Thus, the rejection as to claims 44, 46, and 47 is submitted to be without merit and should be withdrawn. Likewise, claims 73, 75-77, 84, and 86 are directed to specifically defined fragments of SEQ ID NO: 2, and accordingly, the rejection of these claims should also be withdrawn.

Insofar as the instant rejection pertains to claims 72, 78, 81, 83, 87, and 111-114, this rejection is believed overcome and should be withdrawn in view of the above-described amendments to claims 72, 78, 83, 87, and 111 in which the portions of the claims encompassing biologically active fragments and allelic variants have been deleted and the stringent conditions have been more clearly defined. Applicants, of course, reserve to right to pursue the deleted subject matter in a continuing application.

Claims 44, 47, 72-73, 75-78, 81, 83-87, and 111-114 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

This rejection is traversed and reconsideration and withdrawal thereof is respectfully requested for the reasons given hereinbelow.

Initially, Applicants note that Claim 85 was cancelled by the amendment filed on December 19, 2002, and therefore the rejection as to Claim 85 is moot.

Claims 44 and 47 are directed to purified polypeptides comprising specific fragments of SEQ ID NO:2, including the amino acid sequence of SEQ ID NO: 2 from residue 1 to 343, and the amino acid sequence of SEQ ID NO: 2 from residue 1 to 337. It appears as though the Examiner is basing the instant rejection on an alleged lack of written description for the polypeptides of amino acids 1-343 and 1-337 of SEQ ID NO:2. However, the polypeptides of amino acids 1-343 and 1-337 of SEQ ID NO:2 are in fact fully described by their amino acid sequences in the specification. Moreover, the

specification teaches that these soluble forms are IL-13 antagonists and are preferred for use in pharmaceutical compositions (specification page 13, lines 9-20). Example 6 specifically describes the preparation of one such polypeptide (residues 1-337) and Figures 5 and 6 show the inhibition of the binding of IL-13 to its receptor by the soluble polypeptide. Thus, it would have been clear from the specification that the inventors had possession of the soluble forms of the IL-13 receptor protein; that said forms were biologically active as IL-13 antagonists, and that pharmaceutical compositions thereof were useful for inhibiting the binding of IL-13 to its receptor, and hence, for identifying IL-13 agonists or antagonists and for treating allergic conditions and infections. Therefore, the rejection of claims 44 and 47 are 35 U.S.C. § 112, first paragraph, is believed unwarranted and reconsideration thereof is respectfully requested.

Insofar as the instant rejection pertains to claims 72, 73, 75-78, 81, 83, 84, 86, 87, and 111-114, this rejection is believed overcome and should be withdrawn in view of the above-described amendments to claims 72, 78, 83, 87, and 111 in which the portions of the claims encompassing biologically active fragments and allelic variants have been deleted and the stringent conditions have been more clearly defined. Applicants, of course, reserve to right to pursue the deleted subject matter in a continuing application.

In view of the foregoing, this application is believed in condition for favorable reconsideration and such action is earnestly solicited. In the event the Examiner believes the instant amendments and remarks do not put the application in condition for allowance, entry of the amendments is nevertheless requested in order to put the application in better condition for appeal. A Notice of Appeal is attached herewith.

Respectfully submitted,

Date:

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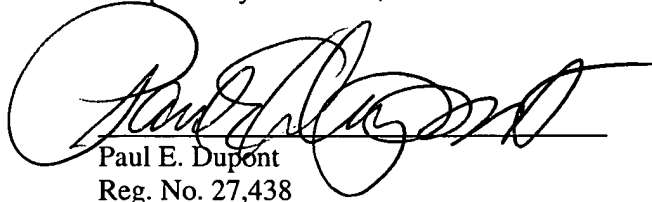
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